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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|--------------------------------|------------------|
| 10/600,937 | 06/20/2003 | Michael Robin Hale | VPI/98-06DIV | 6239 |
| 1473 | 7590 | 09/02/2004 | | |
| FISH & NEAVE 1251 AVENUE OF THE AMERICAS 50TH FLOOR NEW YORK, NY 10020-1105 | | | EXAMINER MCKENZIE, THOMAS C | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1624 | |

DATE MAILED: 09/02/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/600,937

Applicant(s)

HALE ET AL.

Examiner

Thomas McKenzie, Ph.D.

Art Unit

1624

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 June 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,4,13 and 15-27 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1,2,4,13 and 15-27 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

1. This action is in response to an application filed on 12/6/00. There are seventeen claims pending. Claims 1, 2, 4, 13, 15, and 16 are compound claims. Claims 17-19 are composition claim. Claims 20-27 are use claims. The application concerns some NO and N-N sulfonamide compounds, compositions, and uses thereof. Claim 3 appears to be missing.

Election/Restrictions

2. Restriction to one of the following inventions is required under 35 U.S.C.

121:

- I. Claims 1, 2, 15, and 16, the third compound of 13, and parts of 17 and 20-27, drawn to 1,3-diaminosulfonamides of formula I, classified in class 564, subclass 81, among others.
- II. Claim 4, and parts of 17 and 20-27, drawn to heterocycle containing 4-aminobutylsulfonamides of formula III, classified in class 546, subclass 176, among others.
- III. Claims the first, second, sixth, eighth, and ninth compounds of 13, and parts of 17 and 20-27, drawn to 1,2-oxazines, classified in class 544, subclass 63.
- IV. Claims the fourth compound of claim 13, and parts of 17 and 20-27, drawn to bis 1,3-thiazoles, classified in class 548, subclass 204.

Art Unit: 1624

- V. Claims the fifth compound of claim 13, and parts of 17 and 20-27, drawn to 1,3-diazepin-2-one compounds, classified in class 540, subclass 492.
- VI. Claims the sixth compound of claim 13, and parts of 17 and 20-27, drawn to quinoline compounds, classified in class 546, subclass 153.
- VII. Claim 18, and parts of claim 19, drawn to complex compositions, containing a second active ingredient, classified in class 514, subclass 1, among others.

Claim 13 links Groups I and III-VI.

Claims 17 and 20-27 link Groups I-VI.

Claim 19 links Groups I-VIII.

If applicants elect group VII, the complex compositions, then they must also elect a species of added antiviral agent for purposes of classification and examination.

In parent Application 09/731,129 Applicants elected Group I.

3. The inventions are distinct, each from the other because of the following reasons: Inventions I-VII have acquired a separate status in the art as shown by their different classification, thus the patent search required for Group I is not co-extensive with that required for Groups II-IV. The basic names of these heterocycles differ, thus the literature search for these various species will be

divergent. Because these inventions are distinct for the reasons given above, restriction for examination purposes as indicated is proper.

4. Inventions VII and I-VI are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because anti-viral drugs, like ribavirin, with no effect against HIV are well known. The subcombinations I-VI have separate claimed utility such as treatment HIV inventions distinct from treatment of non-retroviral infections. Simple compositions and those with an additional active ingredient are patentably distinct because the combination (complex composition) can be patentable even if the subcombinations (the individual compounds) are not. This is because of the possibility of synergistic interaction, which is usually the purpose of the complex composition in the first place. Because these inventions are distinct for the reasons given above, have acquired a separate status in the art as shown by their different classification, and the search required for Group IV is not required for Group I-III, restriction for examination purposes as indicated is proper.

5. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement is traversed (37 CFR 1.143).

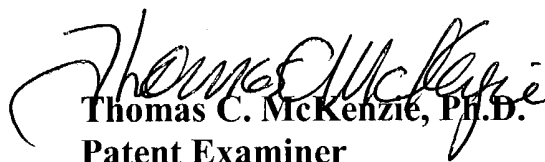
6. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Conclusion

Information regarding the status of an application should be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at (866) 217-9197 (toll-free). Please direct general inquiries to the receptionist whose telephone number is (703) 308-1235.

Art Unit: 1624

Please direct any inquiry concerning this communication or earlier communications from the Examiner to Thomas C McKenzie, Ph. D. whose telephone number is (571) 272-0670. The FAX number for amendments is (703) 872-9306. The PTO presently encourages all applicants to communicate by FAX. The Examiner is available from 8:30 to 5:30, Monday through Friday. If attempts to reach the Examiner by telephone are unsuccessful, please contact James O. Wilson, acting SPE of Art Unit 1624, at (571)-272-0661.


Thomas C. McKenzie, Ph.D.
Patent Examiner
Art Unit 1624
(703) 272-0670

TCMcK/me